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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,574	08/05/2003	Ramin Shiekhatar	WSTR-0014C	1505

7590 06/27/2006

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Marlton, NJ 08053

EXAMINER
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HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/634,574	SHIEKHATTAR, RAMIN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne L. Holleran	1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, (in part, to the extent reads on methods comprising the use of an agent that interacts with nucleic acid sequence), drawn to methods of modulating the activity of at least one component of a BRCA1-BRCA2-containing complex, classified in class 514, subclass 44.
  - II. Claims 1-6 (in part, to the extent reads on methods comprising the use of an agent that interacts with a protein), drawn to methods of modulating the activity of at least one component of a BRCA1-BRCA2-containing complex, classified in class 424, subclass 130.1.
  - III. Claims 7-9, drawn to agents.
  - IV. Claim 10-12, drawn to method for treating cancer comprising using an agent of claims 4, 5 or 6.
  - V. Claim 13, drawn to method for identifying an agent that inhibits expression of BRCC36 or BRE protein, classified in class 435, subclass 6.
  - VI. Claim 14, drawn to an agent.
  - VII. Claim 15, drawn to a method for treating cancer comprising using an agent of claim 14.
  - VIII. Claim 16, drawn to an antibody that recognizes BRCC36 or BRE protein, classified in class 530, subclass 387.1.

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IX. Claim 17 (in part, to extent level of nucleic acids is detected), drawn to a method for diagnosing cancer, classified in class 435, subclass 6.

X. Claim 17 (in part, to extent level of a protein is detected), drawn to method for diagnosing cancer, classified in class 435, subclass 7.1.

2. The inventions are distinct each from the other, for the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of group I require the use of nucleic acids, whereas the methods of group II require the use of protein. Thus, the methods are mutually exclusive and have a materially different design and mode of operation. Additionally, it would place an undue burden on the examiner to have to search and examine the two inventions together because the literature concerning methods for use of nucleic acids is not coextensive with the literature for methods of use of proteins.

Inventions I and IV, V, VII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group I, the claims are drawn to modulating the activity of a complex, where as the methods of group IV are drawn to methods of treating cancer, methods for identifying agent that inhibits expression of BRCC36 or BRE, methods of treating cancer with an

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agent that inhibits expression of BRCC36 or BRE, methods of diagnosing cancer. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature. As such, the search and examination of more than one of the groups would place an undue burden on the examiner.

Inventions II and IV, V, VII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group II, the claims are drawn to modulating the activity of a complex, where as the methods of group IV are drawn to methods of treating cancer, methods for identifying agent that inhibits expression of BRCC36 or BRE, methods of treating cancer with an agent that inhibits expression of BRCC36 or BRE, methods of diagnosing cancer. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature. As such, the search and examination of more than one of the groups would place an undue burden on the examiner.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different processes that have different designs and different modes of operation. In the case of group III, the claims are drawn to agents that modulate the activity of either the nucleic acid or protein product of a BRCA1-BRCA2 complex, whereas the agents of group VI are drawn to agents that inhibit the expression of BRCC36 or BRE protein. Additionally, these agents are

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described only in functional terms. Thus, the search of the different groups would not be coextensive because different steps and reagents would need to be searched in the Patent and non-patent literature based on a function and not on a structure. As such, the search and examination of more than one of the groups together would place an undue burden on the examiner.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, there are multiple methods for treating cancer that rely on materially different products. Furthermore, the agents may be used in in vitro methods of modulating BRCA1-BRCA2 complexes. Therefore, the inventions are distinct. Because of the breadth of scope for the agents of group III, it would place an undue burden on the examiner to search and examine groups III and IV together.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, there are multiple methods for treating cancer that rely on materially different products. Furthermore, the agents may be used in in vitro methods of inhibiting the expression of BRCC36 or BRE. Therefore, the inventions are distinct. Because of

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the breadth of scope for the agents of group VI, it would place an undue burden on the examiner to search and examine groups VI and VII together.

Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody may be used in a method of isolating or purifying a BRCC36 or BRE protein. Therefore, the inventions are distinct. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished



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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
June 26, 2006

A handwritten signature in black ink, consisting of several fluid, overlapping strokes that form a stylized representation of the name Larry R. Helms.

**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**